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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/753,107 | 01/06/2004 | Anton Bittner | ORT1563NP | 2785 |

27777 7590 02/08/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

| EXAMINER | |
|---|---|
| ZHOU, SHUBO | |
| **ART UNIT** | **PAPER NUMBER** |
| 1631 | |

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/753,107 | BITTNER ET AL. | |
| | Examiner | Art Unit | |
| | Shubo (Joe) Zhou | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Restriction/Election Requirement*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method of performing quality control in gene expression involving determination of variation between a desired printing of a microarray and an actual printing of a microarray, classified in class 702, subclass 19.

II. Claims 2-6, drawn to a method of performing quality control in gene expression on a microarray during target sample preparation, involving performing generating dynamic range of values from target sample and spiked controls, classified in class 702, subclass 19.

III. Claim 7, drawn to a method of performing quality control in gene expression on a microarray during background intensity check, involving calculating mean and standard deviation for intensity data from one or more replicate spots on the microarray, classified in class 702, subclass 19.

IV. Claims 8-11, drawn to a method of performing quality control in gene expression on a microarray during scanning of the microarray, involving slide flipping, grid placement and calculating, classified in class 702, subclass 19.

V. Claims 12-36, drawn to a method of performing quality control in gene expression on a microarray during quantitation of an image of the microarray, involving calculating CV for log-transformed intensity data and determining outlier spots, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons.

Inventions of groups I-V are directed to related but distinct processes. The related inventions are distinct if the inventions as claimed are mutually exclusive; are not obvious variants; and are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of the different groups are related because they are used to analyze microarray analysis quality control, but the methods are mutually exclusive, not obvious variants and have different modes of actions, functions and effects. Group I involves determining variation between a desired printing of a microarray and an actual printing of a microarray comprising determining distribution of variations; Group II deals with performing quality control during target sample preparation, involving performing generating dynamic range of values from target sample and spiked controls; Group III deals with performing quality control during background intensity check, involving calculating mean and standard deviation for intensity data from one or more replicate spots on the microarray; Group IV deals with performing quality control during scanning of the microarray, involving slide flipping, grid placement and calculating; and Group V deals with performing quality control during quantitation of an image of the microarray, involving calculating CV for log-transformed intensity data and determining outlier spots. Clearly, the inventions deals with quality control during different stages of microarray analysis, comprises distinct steps, involves distinct parameters, and produce different results. Therefore, the inventions of groups I-V are distinct.

Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art. The search required for the groups are not co-extensive because each

group requires a different non-patent literature search due to their comprising different method steps and producing different results. Thus, there would be serious search burden if both groups were examiner together. Therefore, the restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.

Patent Examiner